510(k) SUMMARY

MAR 20 2013

Prepared:	November 30, 2012
Submitter:	Reprocessing Products Corporation (RPC)
Address:	1643 W. Modern Court Tucson, AZ 85705
Phone:	520-888-5551
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Contact:	Michael Honstein, Chief Operating Officer
Device Trade Name:	E-Z Chek® Blood Leak Test Strips K100-0114
Common or Usual Name:	Blood Leak Test Strips
Device Classification Name:	Strip, Dialysate, Hemodialysis Water, Blood Leak indicator
Product Code:	FJD
Class:	II
Regulation Number:	875.5665, 876.5820
Substantial Equivalence:	The Reprocessing Products Corporation (RPC) E-Z Chek® Blood Leak Test Strips are substantially equivalent to the Serim® Blood Leak Test Strips.
Device Description:	Device is semi-quantitative, reagent test strip comprised of a pad impregnated with chemicals which change color upon contact with blood in dialysate. The pad is attached to a plastic strip for handling.
Intended Use:	The Reprocessing Products Corporation (RPC) E-Z Chek® Blood Leak Test Strips are designed to indicate the presence or absence of blood in dialysate during the hemodialysis procedure. The test strips will measure equal to 0 mg HGB/dL and 0.25 mg HGB/dL in dialysate.
Technological Characteristics:	The detection is based on the pseudoperoxidative activity of hemoglobin and myoglobin, which catalyze the oxidation of an indicator by an organic hydroperoxide producing a color change consistent with the color blocks provided in the labeling.

Performance:	The data confirm the product consistently generates color change which meets the color block for the reference solution concentration. Reference solutions were used to evaluate performance between 0 mg HGB/dL and 0.25 mg HGB/dL Bicarbonate/Acetate dialysate used for hemodialysis treatment. These data demonstrate appropriate performance for use in hemodialysis dialysate used in treatment.
Conclusion:	The Reprocessing Products Corporation (RPC) E-Z Chek® Blood Leak Test Strips have the same intended use as the predicate device. Both test strips are designed to detect the presence or absence of blood in dialysate during hemodialysis treatments. The Reprocessing Products Corporation (RPC) E-Z Chek® Blood Leak Test Strips has no characteristics which raise new types of safety and effectiveness questions. The Reprocessing Products Corporation (RPC) E-Z Chek® Blood Leak Test Strips can be used to detect the presence or absence of blood in dialysate during hemodialysis treatment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 20, 2013

Reprocessing Products Corporation
% Mr. Ted Williams
Quality Assurance/Regulatory Affairs Director
P.O. Box 35849
TUCSON AZ 85740

Re: K123805
Trade/Device Name: E-Z Chek® Blood Leak Test Strips (K100-0114)
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: FJD
Dated: January 29, 2013
Received: February 7, 2013

Dear Mr. Williams:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. ***Statement of Indications for Use:***

510k Number (if known): K123805

Device Name: E-Z Chek® Blood Leak (K100-0114)

Indications for Use: The Reprocessing Product Corporation (RPC) E-Z Chek® Blood Leak Test Strips are indicated for detecting the presence or absence of blood in dialysate during hemodialysis treatments.

Prescription Use _____X_____ AND/OR Over the Counter Use _____
(Part 21 CFR 801 Subpart D) (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K123805